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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/20/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/639,207

Applicant(s)

KAZEMI-ESFARJANI ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 9-26 and 29-79 is/are pending in the application.
- 4a) Of the above claim(s) 47-49 and 51-79 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50 is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 9-14, 17-26, 29-40, 42-46 is/are rejected.
- 7) ☒ Claim(s) 15, 16 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

This Office Action is a response to the "Response" filed 14 January 2003 (Paper No. 11) in reply to the Non-Final Office Action mailed 2 October 2002 (Paper No. 9). Claims 1-3, 5-7, 9-26 and 28-50 were considered in Paper No. 9. Claims 5, 6 and 28 were canceled and claims 1, 10, 11-13, 25, 26 and 29-50 were amended in Paper No. 11. Claims 1-3, 7, 9-26, 29-46 and 50 are pending and under consideration.

Oath/Declaration

Objection to the Declaration is withdrawn in view of the filing of a substitute Declaration (Paper No. 10).

Response to Amendment

Rejection of claims 5, 6 and 28 is rendered moot by cancellation of the claims in Paper No. 11.

Claim Objections

Objection to claim 50 is withdrawn.

Claim Rejections - 35 USC § 112

Rejection of claims 1-3, 5-7, 9-25, 41 and 50 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn.

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Claims 26, 29-40 and 42-46 stand rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter for reasons of record and herein below in the “Response to Arguments”.

Claim Rejections - 35 USC § 102

Rejection of claims 26, 32-34, 40, 41 and 50 under 35 U.S.C. 102(b) as being anticipated by Warrick et al. (1998) *Cell* 93:939-949 as evidenced by Paulson (1997) *Neuron* 19:333-344 is withdrawn.

Claims 37 and 39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Warrick et al. (1998) *Cell* 93:939-949 as evidenced by Paulson (1997) *Neuron* 19:333-344 for reasons of record in Paper No. 9 and herein below in the “Response to Arguments”.

Claim Rejections - 35 USC § 103

Rejection of claims 26 and 42 under 35 U.S.C. 103(a) as being unpatentable over Warrick et al. (*supra*) in view of Rørth (1996) *Proc. Natl. Acad. Sci. U.S.A.* 93:12418-12422 is withdrawn.

Claims 1-3, 7, 9-14 and 17-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Warrick et al. (*supra*) in view of Rørth (1996) *Proc. Natl. Acad. Sci. U.S.A.* 93:12418-12422 for reasons of record in Paper No. 9 and herein below in the “Response to Arguments”.

Response to Arguments**Claim Rejections - 35 USC § 112**

Claims 26, 29-40 and 42-46 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic *D. melanogaster* comprising a transgene containing a plurality of CAG's and at least one CAA sequence encoding a polyglutamine repeat sequence, wherein the repeat comprises at least 100 contiguous glutamine residues and said transgene produces polyglutamine toxicity in said transgenic *D. melanogaster*, does not reasonably provide enablement for any and all transgenic *D. melanogaster* comprising a transgene containing a plurality of CAG's and at least one CAA sequence encoding a polyglutamine repeat sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In response to the outstanding rejection, Applicant has amended the claims such that they recite "*D. melanogaster*" and "P" transposable element. However, as pointed out in the previous office actions, the specification is enabling only for a transgenic *D. melanogaster* having polyglutamine toxicity (see, for example, Paper No. 7, page 5, first full paragraph). The disclosure is silent with regard to how the skilled artisan would use a transgenic *D. melanogaster* comprising transgene containing a plurality of CAG's and at least one CAA sequence encoding a polyglutamine repeat sequence wherein the transgenic *D. melanogaster* does not display polyglutamine toxicity. Amending claim 26 such as to include the limitations of claim 41 would obviate this rejection.

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Claim Rejections - 35 USC § 102

Claims 37 and 39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Warrick et al. (1998) *Cell* 93:939-949 as evidenced by Paulson (1997) *Neuron* 19:333-344.

In response to the outstanding rejection, Applicant has amended claim 26 to recite a polyglutamine sequence “comprising at least 100 contiguous glutamine residues” and argues that Warrick *et al.* does not teach this limitation. This argument is not persuasive because the rejected claims are directed to a transgenic *D. melanogaster* comprising a polyglutamine sequence that is between about 50 and 100 amino acids (claim 37) or between about 50 and 200 amino acids (claim 39) in length. Therefore the transgenic *D. melanogaster* of Warrick *et al.*, comprising a polyglutamine sequence of 78 residues, anticipates the claims.

Claim Rejections - 35 USC § 103

Claims 1-3, 7, 9-14 and 17-25 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Warrick et al. (*supra*) in view of Rørth (1996) *Proc. Natl. Acad. Sci. U.S.A.* 93:12418-12422.

In response to the outstanding rejection, Applicant argues, “[i]n contrast to the presently claimed method, Warrick fails to teach or describe a method that requires identifying an endogenous gene the expression of which is effected by the insertion of a marker sequence...The effect of the insertion can confer increased or decreased polyglutamine toxicity in an organism...while Warrick may teach a method of identifying the effect of expressing a known, non-native gene (i.e., exogenous) on polyglutamine toxicity in *Drosophila*, he certainly fails to

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teach or suggest a method of identifying native *Drosophila* genes not previously associated with modulation of polyglutamine toxicity as targets for modulating polyglutamine toxicity” (page 10).

This argument has been fully considered but is not found persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As pointed out in the previous office action, a method of identifying native *Drosophila* genes not previously associated with modulation of a phenotype arising from mutation of another gene is found in the teachings of Rørth (see the first paragraph on page 10 of Paper No. 9). Therefore, the instant invention as a whole is found in the combined teachings of Warrick and Rørth. Also, Warrick does indeed suggest the instant method in teaching, “[w]e can now use *Drosophila* genetics to identify genes that can delay or prevent deleterious consequences of the polyglutamine-repeat proteins on neuronal integrity” (Warrick, page 948, column 1; also cited in Paper No. 9, page 9). The teachings of Rørth clearly fall within the category of *Drosophila* genetics and, as Rørth teaches, are particularly useful for identifying genes that enhance or suppress the phenotype arising from a mutation in another gene, which is precisely what Warrick teaches should be done using *Drosophila* genetics techniques.

Next, Applicant argues, “[d]espite the availability of Rørth at the time Warrick was published, Warrick never suggests the possibility of identifying endogenous *Drosophila* genes that effect polyglutamine toxicity via a method even remotely related to the method described in Rørth” and suggests that the fact that Warrick did not specifically cite the published work of

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Warrick indicates that the skilled artisan would not have been motivated to combine the teachings. This argument is not persuasive because, as described above, Warrick generally teaches that *Drosophila* genetics can be used for the purpose of identifying genes that can delay or prevent deleterious consequences of the polyglutamine-repeat proteins. The skilled artisan would know that this teaching encompasses the teaching of Rørth without the need for Warrick to specifically point to the teaching. Furthermore, Applicant's argument assumes that the reason Warrick does not specifically cite Rørth is because the utility of the method of Rørth was not apparent to Warrick. However, there is nothing in the cited art to indicate that this is the case.

Likewise, Applicant's assertion that the fact that the inventors were the first to report actual reduction to practice of the claimed method argues that other skilled artisans were not motivated to combine the references in such a way as to achieve the claimed invention, presumes to know the reason behind the failure of others to publish a method which anticipates the instant method. There can be many reasons that an obvious combination of teachings is not reduced to practice and publicly disclosed. Because it is impossible to determine what the actual reason is, an anticipatory reference, published either pre- or post-filing, is not required to demonstrate obviousness under 35 U.S.C. § 103(a). The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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As each of these factual inquires were addressed in the previous Office Action and Applicant has not persuasively argued that the claimed invention would not have been obvious to the ordinary skilled artisan based upon the facts that were available in the art at the time of filing, the claims stand rejected under 35 U.S.C. § 103(a).

New Grounds Necessitated by Amendment

Claim Objections

Claim 1 is objected to because of the following informalities: There is a typographical error in the third line of part (b). It appears that the word “which” should appear between “*melanogaster*” and “comprises”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36, 37 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to transgenic *D. melanogaster* comprising a polyglutamine sequence less than about 100 amino acids in length. There is no antecedent basis for this limitation in claim 26, from which the claims depend, which is limited to a repeat comprising at least 100 contiguous glutamine residues.

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Allowable Subject Matter

Claim 50 is allowed.

Claims 15, 16 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
March 19, 2003

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER